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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/725,178 | 11/29/2000 | Bettina Mockel | P 273989 990168 BT | 8596 |

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EXAMINER

HUTSON, RICHARD G

| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 10/22/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/725,178

Applicant(s)

MOCKEL ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment of the specification, claims 1, 2, 5-7, 22 and 23 and the addition of new claims 24-26, Paper No. 15, 8/9/2002, is acknowledged. Claims 1-7 and 21-26 are at issue and are present for examination.

Applicants' arguments filed on 8/9/2002, Paper No. 15, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

The examiner regrets that an initialed copy of 1449 from the information disclosure statement of 10/12/2002 was not enclosed in the previous office action. A copy is being supplied with this action.

Specification

The disclosure is objected to because of the following informalities:

Applicants have deleted the present abstract and replaced it with a new abstract of the disclosure. The new abstract recites "The invention provides nucleotides sequences encoding the gpm gene, which itself encodes phosphoglycerate mutase..." Nucleotides sequences do not encode genes, but rather nucleotide sequences encode proteins. It is suggested that this be amended to "The invention provides nucleotide[s] sequences which encode phosphoglycerate mutase (gpm) ..."

Appropriate correction is required.

Claim Objections

Claim 6 is objected to because of the following informalities:

Claim 6 part (ii) recites "... degeneracy of the genetic code],". It is believed this should be "... degeneracy of the genetic code,".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 7, 24, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 7 are indefinite in that applicants amendment in which applicants have included all of the limitations of previous claim 2 (from which claims 5 and 7 previously depended) in newly amended claims 5 and 7, make the claims confusing in that many of these limitations are unimportant with respect to the patentability of the claims, given the last limitation of each of the claims, "that the polynucleotide comprises the nucleic acid sequence as shown in SEQ ID NO: 1 (Claim 5) or encodes the polypeptide sequence of SEQ ID NO: 2 (claim 7) and replicates in corynebacterial host cells". It is suggested that the last limitation of each of these claims is the only limitation of the claim that need exist in order to make the claim clear.

Claim 6 is indefinite in that newly amended part (iii) which recites "...the nucleotide sequence shown in SEQ ID NO: 1 in which a sense mutation has been introduced, wherein the mutated nucleotide sequence encodes for a polypeptide having phosphoglycerate mutase activity..." is unclear in that it appears that applicants are attempting to include mutant polynucleotides beyond that of naturally occurring *Corynebacterial* polynucleotides within the scope of the claim. Since claim 6 depends from claim 2 and thus claim 1, which is drawn to isolated corynebacterial polynucleotides, such a broadening of the scope of the claim would not be proper. The above referred to recitation of Claim 6 part (iii) is therefore interpreted as encompassing naturally occurring sense mutations.

It is further noted that applicants amendment 6 part (iii) which recites "...the nucleotide sequence shown in SEQ ID NO: 1 in which a sense mutation has been introduced, wherein the mutated nucleotide sequence encodes for a polypeptide having phosphoglycerate mutase activity..." is interpreted as the nucleotide sequence of SEQ ID NO: 1 with a **single** naturally occurring sense mutation.

Claim 24 is indefinite in the recitation of "hybridizes" as this term is unclear absent a statement of the conditions under which the hybridization reaction is performed. Nucleic acids which will hybridize under some hybridization conditions will not necessarily hybridize under different conditions. As such it is unclear how homologous to the sequence of a gene(nucleic acid) encoding SEQ ID NO:2, a sequence must be to be included within the scope of this claim.

Applicants traverse this rejection as was previously made for claims 1-7 and 21-23 by mistake, when in fact the previous rejection only applied to claim 6, as it applies to new claim 24, on the basis that through the use of functional language, claim 24 defines a discrete group of polynucleotides that must encode a protein having the enzymatic activity of phosphoglycerate mutase. This argument is not found persuasive because while it is generally understood that in order to maintain a functional limitation of the claimed genus, those molecules within this genus must maintain a certain degree of similarity to the disclosed polynucleotide of SEQ ID NO: 1, the "structural relationship to SEQ ID NO: 1" of those molecules in the claimed genus remains indefinite, absent a disclosure of what this relationship is.

Claims 25 and 26 are indefinite in that it is unclear what the recitations "...having the function of a primer in a polymerase chain reaction to produce a polynucleotide encoding a protein comprising the amino acid sequence of SEQ ID NO: 2." (claim 25) and "...having the function of a probe in a hybridization reaction to detect or isolate a polynucleotide encoding a protein comprising the amino acid sequence of SEQ ID NO: 2." (claim 26) refer to. Are each of these recitations meant to define the function of the claimed polynucleotide or of the 30 consecutive nucleotides which are comprised by the claimed polynucleotide?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 21-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action.

Applicants traverse this rejection on the basis that claims 1 and 6 have been amended to include the requirement that the variously claimed polynucleotides encode a polypeptide having phosphoglycerate mutase activity and therefore claims 1 and 6 are directed to a discrete and finite number of polynucleotides and neither lack written descriptive support nor are the claims broader than the enabling disclosure. Applicants argument is not found persuasive. First applicants attention is drawn to claim 1, part a) which recites "...a polynucleotide that is at least 70% identical to a polynucleotide encoding a polypeptide containing the amino acid sequence of SEQ ID NO: 2, the polypeptide having phosphoglycerate mutase activity" The polynucleotide of the claimed genus need not encode a polypeptide which has phosphoglycerate mutase activity, but merely be 70% identical to a polynucleotide which encodes a polypeptide which has phosphoglycerate mutase activity. Thus applicants traversal of this rejection on the basis that the claimed polynucleotides encode a polypeptide which has phosphoglycerate mutase activity is flawed.

Further, claim 1 part d) which is drawn to a polynucleotide containing at least 15 consecutive bases of the polynucleotide sequence of a), b) or c), the polynucleotide

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encoding a polypeptide having phosphoglycerate mutase activity remains an inadequate structural description of the claimed genus. The specification provides a single representative species, SEQ ID NO: 1, isolated from *Corynebacteria glutamicum* encompassed by these claims. SEQ ID NO: 1 is a 1020 bp cDNA that encodes a 248 amino acid protein (SEQ ID NO: 2). This portion of the claim which is drawn to all polynucleotides which comprise a mere 15 consecutive bases of the disclosed 1020 bases encompasses an infinite number of polynucleotides encoding variant phosphoglycerate mutases, none of which have been disclosed by the instant specification.

Applicants amendment of claim 6, such that claim 6 part (iii) recites "...the nucleotide sequence shown in SEQ ID NO: 1 in which a sense mutation has been introduced, wherein the mutated nucleotide sequence encodes for a polypeptide having phosphoglycerate mutase activity..." is interpreted as the nucleotide sequence of SEQ ID NO: 1 with a **single** sense mutation, wherein said polynucleotide encodes a polypeptide having phosphoglycerate mutase activity (See also above discussion under 112 2nd paragraph rejection).

Further, applicants have not described those characteristics which make a polynucleotide a "*corynebacterial* polynucleotide".

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

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Claims 1-4, 21-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding a polypeptide which is at least 90% identical to SEQ ID NO: 2, wherein said polypeptide has phosphoglycerate mutase enzymatic activity, does not reasonably provide enablement for any polynucleotide encoding a polypeptide which is at least 70% identical to SEQ ID NO: 2, which hybridizes to a polynucleotide which encodes SEQ ID NO: 2 or comprises at least 15 consecutive bases of SEQ IS NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action.

Applicants traverse this rejection as they traversed the above 112 1st written description rejection on the basis that claims 1 and 6 have been amended to include the requirement that the variously claimed polynucleotides encode a polypeptide having phosphoglycerate mutase activity and therefore claims 1 and 6 are directed to a discrete and finite number of polynucleotides and neither lack written descriptive support nor are the claims broader than the enabling disclosure. This argument is not found persuasive for the reasons discussed above. " As discussed above, applicants amendment has not resulted in the polynucleotides of the claimed genus being limited to those that encode a polypeptide which has phosphoglycerate mutase activity. Thus applicants argument is flawed.

Further as discussed above, claim 1 part d), which is drawn to all polynucleotides which comprise a mere 15 consecutive bases of the disclosed 1020 bases

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encompasses an infinite number of mutant polynucleotides encoding variant phosphoglycerate mutases, none of which have been disclosed by the instant specification. Applicants have given no direction or guidance with respect to these variant polynucleotides, beyond the disclosure of SEQ ID NO: 1.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-4, 6 and 21 under 35 U.S.C. 102(a) as being anticipated by White et al. (Journal of Bacteriology, Vol. 174, No. 2, pages 434-440, January 1992, IDS Reference "TR") has been withdrawn, based on applicants arguments and amendment of claim 1, such that the genus of claimed polynucleotides is drawn to "an isolated corynebacterial polynucleotide" and thus is drawn to those isolated polynucleotides naturally occurring in corynebacteria.

Remarks

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

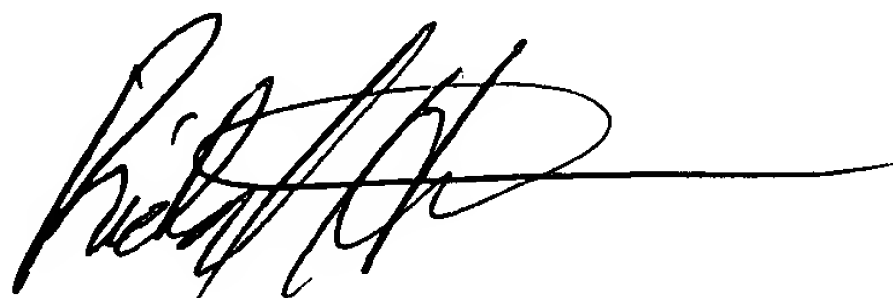
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned

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are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a long horizontal line extending to the right.

Richard Hutson, Ph.D.
Patent Examiner
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October 21, 2002